

Applicants: A. Wesley Prais et al.
Application No.: 10/634,567
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REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-28 and 31-59 are in the application. Through this Amendment, the specification has been amended, in particular, to add language which tracks claim 38. In addition, claims 1, 19, 28, 38 and 50 have been amended.

At the onset, the undersigned would like to thank the Examiner for courtesies extended during a personal interview conducted on July 26, 2007.

In the Official Action, the Examiner provisionally rejected claims 1-28 and 31-59 on the ground of non-statutory obviousness-type double patenting as being allegedly unpatentable over claims 1-64 of co-pending Application No. 10/635,066. In response, a terminal disclaimer is submitted herewith. It is respectfully submitted that the double patenting rejection has been overcome.

I. Rejection Under 35 U.S.C. §103(a) Over Baldwin et al. Or Berke et al.

A. Baldwin et al. and Berke et al. fail to disclose all of the claim limitations.

The Examiner rejected claims 1-8, 19-25, 28 and 31-47 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. (U.S. Patent No. 3,071,135) or Berke et al. (U.S. Patent No. 4,561,445). The Examiner asserted that "Baldwin et al. or Berke et al. meets the claim limitations as described above except for the specific needle diameters, materials, syringe barrel, bevel lengths and rotational angles." The Examiner asserted that it would have been obvious to obtain these features.

Baldwin et al. is directed to a hollow needle. The needle includes a beveled front face 12 which includes beveled side faces 13. A heel surface 15 is also provided. (Col. 3, ll. 12-16). The heel surface is “dished” to define a depression or recess 17, as clearly shown in Fig. 3. (Col. 3, ll. 41-50).

Berke et al. is directed to a needle which includes an internal solid cylinder 10', which acts as an inner electrode. (Col. 3, ll. 49-51). The solid cylinder 10' is surrounded by a cylinder 11 of insulating material. (Col. 3, ll. 52-53). Berke et al. describes a process of preparing multiple facets on the needle about the solid electrode to provide a finished configuration as shown in Figs. 10 and 11. (Col. 4, l. 1 – col. 5, l. 28). As shown in Figs. 10 and 11, facets extend from the insulating cylinder 11 to a sharpened point. Facets 22 and 24 are located on one side of the sharpened point while the facets 34 and 36 define the opposite side of the sharpened point. (See, Fig. 12). A flat surface also extends from the insulating cylinder 11, extending in a rightward direction as shown in Fig. 10. In all, three facets are located about the insulating core 11 of Berke et al.

1. Claim 1

Claim 1 is directed to a syringe assembly which includes a needle cannula having “a multi-beveled point including a plurality of planar bevels extending at different angles relative to said central axis, including a primary bevel, a pair of tip bevels and a pair of middle bevels” with “each of said bevels is generally flat.” In contrast, Baldwin et al. does not provide at least five planar bevels in its device. As clearly shown in Fig. 3, the recess 17 is dished and not formed

planar. Also, the shape of the heel 15 about the recess 17 is unclear, as well as, the shape of the beveled side faces 13 is unclear. In any regard, at least five planar surfaces, which are flat, are not shown or disclosed in Baldwin et al. Moreover, there is no suggestion or motivation to modify Baldwin et al., since the recess 17 must be dished. (See, col. 3, ll. 41-50).

Berke et al. discloses the use of a plurality of facets. However, as shown in Fig. 11, the facets 22, 24, 34, 36 which meet and define the point of the needle, are shown to have curved surfaces. Berke et al. refers to elliptical configurations in describing the grinding processes for forming the needle. (See, e.g., col. 4, ll. 4-8). In sum, Berke et al. does not disclose or suggest the use of flat planar bevels. It is respectfully submitted that claim 1, along with dependent claims 2-8, are patentable over Baldwin et al. and Berke et al.

2. Claim 19

Claim 19 is directed to a syringe assembly which includes a needle cannula having a multi-beveled point "comprised of a primary bevel, a pair of tip bevels, and a pair of middle bevels" wherein "said planar angles of said primary bevel and said pair of middle bevels are substantially equal." There is no disclosure or suggestion in Baldwin et al. of what angles are to be used in forming the side faces 13, the heel 15, or the recess 17. As such, there is no disclosure or suggestion of having a planar angle for at least three different bevels be substantially equal (i.e., the planar angle of a primary bevel plus the planar angle of a pair of middle bevels).

In addition, there is no disclosure or suggestion in Berke et al. of what angles are to be used in forming the facets 22, 24, 34 or 36. As with Baldwin et al., there is no disclosure or

suggestion of having a planar angle for at least three different bevels be substantially equal in Berke et al. It is respectfully submitted that claim 19, along with dependent claims 20-25, are patentable over Baldwin et al. and Berke et al.

3. Claim 28

Claim 28 is directed to a syringe assembly which includes a needle cannula having a multi-beveled point "comprised of five bevels, wherein each of said five bevels is provided on said cannula at a planar angle defined between said central axis and a reference plane" and "wherein each of said five bevels is provided on said cannula at an angle of rotation about said central axis, a reference axis being disposed perpendicularly to said central axis". Further, "a first planar angle is defined at said bevel corresponding to a first rotational angle, said first rotational angle being measured from said reference axis, a second planar angle is defined at said bevel corresponding to a second rotational angle, said second rotational angle being measured from said reference axis, said first and second rotational angles being different with said first and second planar angles being substantially equal." Baldwin et al. does not provide such an arrangement. Both portions of the heel 15 are located at the same rotational angle relative to a central axis, while both side faces 13 are also located at the same rotational angle relative to the central axis. As discussed above, there is no disclosure in Baldwin et al. of planar angles. Even taking that both of the side faces 13 may be formed at the same planar angle or that both of the heel portions 15 about the recess 17 may be formed at the same planar angle, both side faces 13 and both heel portions 15 are at the same, not different, rotational angles relative to each other;

there is no disclosure or suggestion in Baldwin et al. to have bevels at two different rotational-angle locations with the same planar angle. In other words, there is no disclosure or suggestion to have two or more of a side face 13, a heel portion 15, and/or recess 17 at the same planar angle.

Berke et al. suffers from the same deficiencies of Baldwin et al. As discussed above, Berke et al. does not disclose planar angles. As such, there is no disclosure to have bevels with planar angles being substantially equal. It is respectfully submitted that claim 28, along with dependent claims 31-35, are patentable over Baldwin et al. and Berke et al.

4. Claim 38

Claim 38 is directed to a syringe assembly which includes a needle cannula having "first, second, third, fourth and fifth bevels contiguously bounding" an opening defined through a first end of the needle cannula. The bevels are arranged in a specific contiguous sequence "wherein said first and third bevels each have a greater length than each of said second bevel, said fourth bevel, and said fifth bevel." The specification has been amended to show an example of this arrangement. Baldwin et al. fails to disclose such an arrangement. With the specific claimed contiguous sequence, two bevels must be separated by a bevel of shorter length with those separated bevels being also greater in length than two other formed bevels. With respect to Baldwin et al., it can be argued that portions of the heel 15 about the recess 17 have greater length than the recess 17. However, the side faces 13 clearly have greater length than the heel

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portions 15. Claim 38 would require Baldwin et al. to have heel portions 15 with greater length than the side faces 13.

With respect to Berke et al., Berke et al. fails to disclose an opening bound by five bevels. A solid cylinder 10' is disposed in the needle of Berke et al., rather than an opening. Moreover, at best three bevels may be considered to contiguously bound the solid cylinder 10'. There is no suggestion to modify Berke et al. to avoid this arrangement. It is respectfully submitted that claim 38, along with dependent claims 39-47, are patentable over Baldwin et al. and Berke et al.

B. Claimed Features Are Non-Obvious

In the Official Action, the Examiner asserted that the claimed needle ranges are "obvious since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice...and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art." The Examiner's assertions are respectfully traversed.

The claimed ranges, including angles and cannula thicknesses, are critical limitations which provide meaningful and beneficial results. These limitations are not the result of optimization or routine experimentation. In the context of the invention as claimed, including the specific bevel arrangement, it has been found that the subject invention provides reduced needle penetration forces as compared to existing products. Paragraph [0049] and the following

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table in Applicants' specification set forth the obtainable improvement based on the inventive arrangement. It is respectfully submitted that the claimed ranges are critical and non-obvious in obtaining these tangible improvements. This criticality further supports the patentability of claims 1-8, 19-25, 28 and 31-47 over Baldwin et al. and Berke et al.

II. Rejection Under 35 U.S.C. §103(a) Over Hickey

The Examiner rejected claim 50 under 35 U.S.C. §103(a) as being allegedly unpatentable over Hickey (U.S. Patent No. 2,697,438). The Examiner asserted that "Hickley [sic] discloses a needle cannula (Figure 1) with a plurality of discrete bevels (Figure 3) (10, 8) wherein one of said plurality of discrete bevels is located furthest from said point and has a shorter length than any other (8) (Figures 1-4)."

Hickey is directed to a noncoring hypodermic needle which discloses an opening 7 bound by bevel surfaces 10 and cylindrical surface 8. It is the Examiner's position that the cylindrical surface 8 is formed with a shorter length than either of the bevel surfaces 10. The Examiner's assertion is respectfully traversed.

As shown in Fig. 2 of Hickey, the cylindrical surface 8 has an arcuate profile. It is completely unclear if the horseshoe-shape of the cylindrical surface 8 has a greater or shorter length than either of the bevel surfaces 10, particularly in view of the arcuate profile. In other words, as shown in Fig. 4, the cylindrical surface 8 has a greater length due to its arcuate shape than if it was formed flat. It is further noted that there is no disclosure or discussion in Hickey of the respective lengths of the cylindrical surface 8 and the bevel surfaces 10. The Examiner is

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solely relying on the figures for relative lengths. Applicants would like to point out MPEP §2125, which indicates that portions of features in a drawing can not be relied upon alone in formulating a rejection where there is no indication that drawings are to scale. (See, MPEP §2125 (“When the reference does not disclose that the drawings are to scale and are silent as to dimensions, arguments based on measurements of the drawing features are of little value.”)). There is no indication that the drawings in Hickey are to scale. It is respectfully submitted that the drawings of Hickey can not be relied upon in formulating a rejection herein. It is further respectfully submitted that claim 50 is patentable over Hickey.

III. Rejection of Claims 51-57 Over Hickey In View of Baldwin et al. Or Berke et al.

The Examiner rejected claims 51-57 under 35 U.S.C. §103(a) as being allegedly unpatentable over Hickey in view of Baldwin et al. or Berke et al. The Examiner asserted that Hickey meets the claimed limitations “except for the additional needle bevels and rotational angles.” The Examiner asserted that Baldwin et al. or Berke et al. overcome these deficiencies.

As noted above, Baldwin et al. and Berke et al. do not provide any details as to planar angles or rotational angles, nor does either reference provide details as to relative lengths of bevel surfaces. As such, Baldwin et al. and Berke et al. fail to overcome the deficiencies of Hickey noted above. It is further noted that the claimed limitations provide critical and meaningful advantages over the prior art, as discussed above. The limitations of claims 51-57 are not merely obvious over the cited prior art. It is respectfully submitted that claims 51-57 are patentable over Hickey, Baldwin et al. and Berke et al., each taken alone or in combination.

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IV. Rejection Under 35 U.S.C. §103(a) Over Baldwin et al. Or Berke et al. Or Hickey In View Of Hausser

The Examiner rejected claims 9-10, 26-27, 36-37, 48-49 and 58-59 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. or Berke et al. or Hickey in view of Hausser (U.S. Patent No. 5,385,555). The Examiner asserted that the primary references meet the claimed limitations “except for a needle shield with a specific Shore hardness as claimed.” The Examiner relied on Hausser for allegedly overcoming this deficiency.

As set forth at col. 5, ll. 40-43, the safety shield in Hausser is disclosed as being formed generically from a “thermoplastic material”. The rejected claims of the subject application are directed to a specific material, particularly a styrene block thermoplastic elastomer, which is absolutely not disclosed or suggested in Hausser. The advantages of this specific material are discussed extensively in Applicants’ specification, such as at paras. [0033] - [0041].

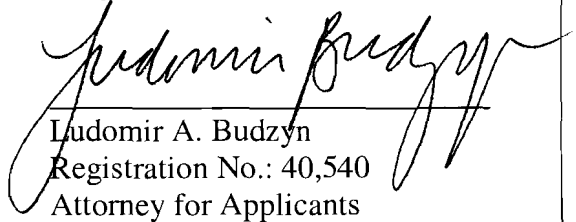
Preservation of needle sharpness and improved sterilization are some of the obtained benefits of the claimed material and this material is not at all obvious from Hausser. It is respectfully submitted that claims 9-10, 26-27, 36-37, 48-49 and 58-59 each provide additional bases of patentability beyond that discussed above and are each, in turn, patentable over Baldwin et al., Berke et al., Hickey and Hausser, each taken alone or in combination.

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V. Conclusion

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,


Ludomir A. Budzyn
Registration No.: 40,540
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700